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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,319	08/08/2001	Gerard P. McNally	MCP-0289	5350

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,319	MCNALLY ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,8,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,8,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Submission under MPEP 609D(1/30/2006).

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3,5,8,14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 5,599,577) in view of Drug Launches (1993), Schmidt et al. (US 5,418,220), oltmann et al. and Gaginella et al..

Stevens et al. disclose the combination of simethicone, preferably in the range of 20 mg to about 125 mg per dosage unit, generally not to exceed 500 mg/day, to a patient suffering from gas and a pharmaceutical suitable for treatment of gastrointestinal disorders (Column 4, lines 38-54).

Drug Launches (1993) discloses the combination of simethicone and 10 mg of bisacodyl which is used to treat constipation, facilitate bowel motion and evacuation of intestines (Abstract).

Schmidt et al. (US 5,418,220) disclose that simethicone is effective in treating constipation (Column 2, lines 35-68, Column 3, lines 1-3, Claims 2,7,8).

Holtmann et al. teaches that simethicone is effective in treating dyspepsia associated with disturbance with GI motility in addition to its effects on gas-related symptoms and that simethicone may stimulate gastrointestinal motility (see entire reference, especially, Pg. 1464).

Gaginella et al.. discloses that bisacodyl significantly increased transit of marker through the small intestine (Pg. 1242).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of bisacodyl and 10 to 500 mg of simethicone or a method of improving small bowel motility in a human or for enhancing the small bowel motility increasing effect of bisacodyl by administering said composition. However, the prior art amply suggest the same as the prior art discloses the combination of simethicone in the claimed dose with pharmaceutical which is suitable for treatment of GI disorders, that bisacodyl and simethicone are suitable for treatment of constipation, that bisacodyl increases transit of a marker through the small intestine and that simethicone may increase GI motitility. As such, it would have been well within the skill of and one of ordinary skill in the art to modify the prior art as above with the expectation that the combination of simethicone and bisacodyl would be suitable for treatment of constipation and be effective increasing small bowel motility.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

As indicated above, there is no requirement that Steven's disclose the entire claimed invention. Further, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). As such, the fact that diarrhea agents are specified does not preclude the use of other GI disorder agents.

As indicated above, there is no requirement that Gaginella disclose the entire invention. Further, absent evidence showing criticality of the amount ranges, it is well within the skill of one of ordinary skill in the art to adjust dosages based of effectiveness of treatment. Since the prior art suggests the combination of simethicone and bisacodyl for treatment of constipation, one of ordinary skill in the art would expect compared to bisacodyl alone that less bisacodyl would be necessary.

Intestinal gas and nitric oxide as disclosed in Gaginella have no relation to each other. Intestinal gas is in the lumen of the GI. Nitric oxide as disclosed in Gaginella is a neurotransmitter between cells and there is no indication in Gaginella that nitric oxide is in the form of a gas in the lumen of the intestine (See Fig. 5 of Gaginella). Even if nitric oxide was present as a gas in the lumen, Applicant has provided no evidence the effect on intestinal gas by simethicone would have any effect on the function of nitric oxide.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
April 3, 2006

JOHN PAK
PRIMARY EXAMINER
GROUP 1600